IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9063

Bartle, J. May 10, 2013

Janice Phillips ("Ms. Phillips" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In July, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting cardiologist, Gregory R. Boxberger, M.D., F.A.C.C. Based on an echocardiogram dated June 27, 2002, Dr. Boxberger attested in Part II of claimant's Green Form that Ms. Phillips suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $518,044.[3]

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of
(continued...)

In the report of claimant's echocardiogram, Dr. Boxberger stated that claimant had a "[n]ormal left ventricular size, with systolic performance estimated in the range of 55%." An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See Settlement Agreement § IV.B.2.c.(2)(b)iv).

In September, 2003, the Trust forwarded the claim for review by James W. Mathewson, M.D., one of its auditing cardiologists. In audit, Dr. Mathewson concluded that there was no reasonable medical basis for Dr. Boxberger's finding of a reduced ejection fraction in the range of 50% to 60%. Dr. Mathewson explained:

> The qualitative and quantitative measures of left ventricular ejection fraction are normal. My measurements of LVIDd and LVIDs are 46 and 29mm respectively. The LV apex moves normally in systole. The estimated ejection fraction with these numbers is about 70%. The LV shortening fracitgon [sic] is 37% consistant [sic] with this finding.

Based on the auditing cardiologist's finding that claimant did not have a reduced ejection fraction, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit

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3. (...continued)
the five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). A reduced ejection fraction is one of the complicating factors needed to qualify for a Level II claim. Although the Trust contests claimant's level of mitral regurgitation, we need not resolve this dispute given our determination as to claimant's ejection fraction.

Rules"), claimant contested this adverse determination.[4] In contest, claimant submitted affidavits of Dr. Boxberger, Robert W. Evans, M.D., F.A.C.P., F.A.C.C., and G. Whitney Reader, M.D., F.A.C.P., F.A.C.C. Each of these physicians recognized that claimant's ejection fraction was more than 60%, but concluded that it was reasonable for the attesting physician to state that claimant had a reduced ejection fraction in the range of 50% to 60%. Claimant argued, therefore, that there was a reasonable medical basis for her claim because three Board Certified cardiologists independently agreed that she had a reduced ejection fraction. Claimant further asserted that the auditing cardiologist "apparently did not understand the difference between his **personal opinion** ... and the 'reasonable medical basis' standard."

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Mathewson submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Phillips had a reduced ejection fraction. In support of this conclusion, Dr. Mathewson stated:

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4. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

> Upon review I also affirmed my findings that the qualitative and quantitative measures of Claimant's left ventricular ejection fraction are normal. Visually, the ejection fraction is greater than 60%. The left ventricular apex is moving normally in systole. My measurements of LVIDd and LVIDs (at 46 and 29 mm, respectively) confirm that Claimant's ejection fraction is approximately 70% and the left ventricular shortening fraction is 37%. There is no reasonable medical basis for a finding of a reduced ejection fraction less than or equal to 60%.

The Trust then issued a final post-audit determination, again denying the claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On May 3, 2004 we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3492 (May 3, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on October 8, 2004, and claimant submitted a sur-reply on October 22, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[5] to review claims after the Trust and

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5. A "[Technical] [A]dvisor's role is to act as a sounding board (continued...)

claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D. F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The show cause record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she suffered from a reduced ejection fraction. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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5. (...continued)
for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of her claim, Ms. Phillips repeats the arguments she made in contest, namely, that the opinions of Dr. Boxberger, Dr. Evans, and Dr. Reader provide a reasonable medical basis for the finding of a reduced ejection fraction. In addition, claimant contends that the concept of inter-reader variability accounts for the differences between the opinions provided by claimant's physicians and the auditing cardiologist, Dr. Mathewson. According to claimant, there is an "absolute" inter-reader variability of 18% when evaluating an ejection fraction using Simpson's Rule, 16% when using the wall motion index, and 19% when using subjective visual assessment. Thus, Ms. Phillips contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that an ejection fraction is as high as 79%, a finding of an ejection fraction of 60% by an attesting physician is medically reasonable.

In response, the Trust argues that the opinions of claimant's physicians do not establish a reasonable medical basis for her claim because they concede that claimant's ejection fraction was greater than 60% and fail to explain why it would be reasonable to say that her ejection fraction was in the range of 50% to 60%. The Trust also contends that inter-reader variability does not establish a reasonable medical basis for this claim because Dr. Mathewson specifically determined that

there was no reasonable medical basis for the attesting physician's finding.[6]

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Phillips had a reduced ejection fraction. Specifically, Dr. Vigilante determined,

> The left ventricle was normal in size and completely normal in contractility. In fact, there was hyperdynamic contractility particularly noted in the apical two chamber view at 10:04:45 on the tape. The ejection fraction was greater than 70%.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, claimant does not adequately refute the findings of the auditing cardiologist or the Technical Advisor. Claimant does not rebut Dr. Mathewson's determination that his "measurements of [claimant's] LVIDd and LVIDs (at 46 and 29 mm, respectively)

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6. The Trust also argues that Audit Rule 18(b) prohibits the submission of more than one expert report. We disagree. We previously have declined to impose a limitation on the number of verified expert opinions that may be submitted by a claimant. See, e.g., PTO No. 7111 at 6 n.9 (Apr. 12, 2007). In addition, the Trust argues that claimant's additional expert reports should be disregarded because Ms. Phillips did not disclose their compensation or submit a list of previous cases in which they have served. Again, we disagree. As we previously have held, requiring disclosures pursuant to Rule 26(a)(2) of the Federal Rules of Civil Procedure would serve no purpose given the prohibition on discovery contained in the Audit Rules. See, e.g., PTO No. 6996 at 7 n.10 (Feb. 26, 2007).

confirm that Claimant's ejection fraction is approximately 70%."[7] Nor does claimant challenge Dr. Vigilante's conclusion that "[t]he left ventricle was normal in size," "completely normal in contractility," and "greater than 70%."[8] Neither claimant nor her experts identified any particular error in the conclusions of the auditing cardiologist and Technical Advisor. Mere disagreement with the auditing cardiologist and Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

Moreover, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Phillips had a reduced ejection fraction is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the auditing cardiologist determined that claimant had an ejection fraction of "about 70%" and the Technical Advisor concluded that claimant's ejection fraction was "greater than 70%." Adopting claimant's argument that inter-reader variability would expand the range of a reduced ejection fraction by as much as ±19% would allow, as noted above,

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7. For this reason as well, we reject claimant's argument that the auditing cardiologist simply substituted his personal opinion for the diagnosis of the attesting physician.

8. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

a claimant to recover benefits with an ejection fraction as high as 79%. This result would render meaningless this critical provision of the Settlement Agreement.[9]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had a reduced ejection fraction. Therefore, we affirm the Trust's denial of the claim of Ms. Phillips for Matrix Benefits.

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9. Moreover, the Technical Advisor specifically took into account the concept of inter-reader variability as reflected in his statement that, "Even taking into consideration the issue of inter-reader variability, it would be impossible for a reasonable echocardiographer to conclude that the Claimant's ejection fraction was in the range of 50% - 60%."